Title: Single-Use Hygiene Items

Description

The invention relates to a single-use hygiene item, such as a diaper, an incontinence article or a sanitary napkin, having an absorbent element for absorbing and retaining bodily fluids and having an analysis device for the bodily fluid.

Hygiene items are known which have indicator strips which undergo a change in color when wetted with urine and thus indicate in a visually perceptible manner when they are saturated. Since these indicator strips, in the broadest sense, represent an analysis device for the bodily fluid, the point of departure in the characterizing portion was a hygiene item having an analysis device.

However, in the case of hygiene items there is not only the necessity of monitoring their state of saturation and of indicating when the hygiene item is in a depleted condition, there is the fundamental need to analyze urine, for example, with respect to its composition. Consequently, the proposal is put forward in EP 0 438 482 B1 to provide an analysis device in a urine collection bag with indicating devices exposed to urine. Specifically, they are indicating devices which analyze the urine reaching the urine collection bag for its pH, nitrite, leukocyte, glucose and electrolyte values. The indicating devices are initially white and change color after being wetted with the urine to be analyzed. In an acidic medium, for example, a section of a pH-value indicator will turn yellow and in an alkaline medium it will turn blue. Analysis devices, identified as control cards, are described, having a color chart with several colors under a particular indicator section, by means of which a user can assign the color reaction of the indicator being monitored to a value. This value is given in another line below the color chart.

According to the teaching of this publication, each particular indicator panel on the urine-exposed side is covered by a membrane which has perforations consisting of extremely small holes. This membrane forms a type of metering device and allows the urine to reach the indicator panel only very slowly. In this way an initial flow of urine entering the empty collection bag with a high concentration of germs is prevented from causing a supercritical display which cannot normally be triggered by the main urine stream. In the same way, the residual urine, which differs

from the main stream, also cannot determine the reading by itself. As a result of the relatively slowed down passage through the membrane, the urine to be analyzed is brought to the indicator panel "well mixed." In an advantageous further configuration of the analysis device, this publication describes that the indicator substances of the indicator field are embedded in a material which swells in the presence of moisture. In this way, as the material swells, pressure is built up against the membrane, and as a result the passage of urine is rendered even more difficult. In this way, flushing out of the color-creating indicator substances is counteracted, and an unbiased, accurate reading of the quasi-frozen display values can be taken even after many hours.

Whenever analysis devices are used, an effort is made, or a need even exists, to ensure that the substances to be analyzed come into contact in as unadulterated a form as possible with the measurement-sensitive means, that is to say with the indicators on the analysis device, to ensure as accurate a measurement result as possible, free of any interaction.

For this reason the analysis device in accordance with the aforementioned EP 043842 B1 was also located in a urine routing system connected to a urethral catheter in the form of a urine collection bag.

This is naturally experienced as unpleasant by patients whose bodily fluid is to be subjected to analysis. In addition, it is a medically complicated procedure. In the case of incontinent persons the possibility also does not exist of passing the bodily fluid to be analyzed into a container for purposes of analysis. Using this as the starting point, the object of the present invention is to expand the application of an intrinsically familiar analysis device described in EP 0 438 482 B1, specifically to render the use of a urine routing system attached to a urethral catheter unnecessary.

This object is fulfilled through the use of an analysis device in accordance with the invention for measuring the composition of the bodily fluids, specifically for measuring pH, nitrite, leukocyte, glucose and/or electrolyte values of urine or blood, in a single-use hygiene item with an absorbent element for absorbing and retaining bodily fluids, as for example, a diaper, an incontinence article or a sanitary napkin (claim 15).

As a result of the use in accordance with the invention it becomes possible for the first time to employ analysis devices for measuring the composition of bodily fluids outside a urine routing system. With the invention, protection is therefore also being claimed for an intrinisically familiar hygiene item which has an analysis device for measuring the composition of the bodily fluid to be absorbed, specifically for measuring pH, nitrite, leukocyte, glucose and/or electrolyte values.

In a further development of this concept, a hygiene item of the type described at the outset is proposed, which, in accordance with the invention, is characterized in that the analysis device is disposed at a place on the hygiene item which can be impinged upon by the bodily fluid to be analyzed and is separated by means of a separating means in an essentially fluid-tight manner from the absorbent element, so that bodily fluid passed by a user to be analyzed can reach the analysis device directly, but bodily fluid passed into the absorbent element is retained by the separating means and kept away from the analysis device (claim 1).

The embodiment of the hygiene item according to the invention has the advantage that bodily fluid to be analyzed is not affected by interaction with absorbent element materials in the hygiene article which may be present and/or by the leaching out of substances from the absorbent element material which affect the analysis reaction, and thus falsify the result of the measurement. For example, the absorbent element of modern hygiene items normally comprises so-called superabsorbent polymer materials, which retain many times their own weight in fluid. These substances, however, have a falsifying effect on the measurement of individual components. Due to the fact that the analysis device is separated by the aforementioned separating means in a basically fluid-tight manner from the absorbent element of the hygiene item, it is ensured that urine which was biased as a result of the interaction with the materials of the absorbent element with respect to the analysis reaction, does not reach the analysis device and is not analyzed there.

The separating means could, in the simplest instance, comprise an essentially fluid-impermeable layer of film. The separating means in a further development of the invention forms an insert in the hygiene item containing the analysis device and/or in the absorbent element of the hygiene item. The term

"insert" is to be understood as an area of the hygiene item separated by the separating means from the remainder of the absorbent element. This insert or area can, for example, be dish-shaped and have side walls extending up on the side facing the body.

Under a further embodiment of the hygiene item according to the invention, edges of this insert are folded over on its top side.

The insert is advantageously delineated by a fluid-impermeable film , which simultaneously forms the separating means.

The separating means and/or the insert could be disposed as a relatively shallow elevation on the upper side of the absorbent element of the hygiene item, so that the insert is impinged upon first by the bodily fluid passed by a user of the hygiene item, which can then penetrate into the adjacent areas of the absorbent element after the insert is filled.

Under a further advantageous embodiment of the invention, the insert is located essentially flush over its surface with the top side of the absorbent element facing the body.

In essence, the analysis device could be disposed in any way at all, separated by the separating means from the absorbent element. In a further development of the invention, however, it is proposed that the analysis device is disposed resting against one side of the separating means. When the hygiene item is impinged upon by bodily fluid, the latter will normally travel as far as the separating means following gravity and there come into contact with the analysis device.

A standard, familiar hygiene item, for example, a diaper, an incontinence article or a sanitary napkin, can be made in accordance with the present invention, having an analysis device to measure and check the composition of bodily fluids. Figures 1 to 3 provide an initial embodiment of an insert 2 which can be integrated into a standard hygiene item with an analysis device 4 located in it. The insert 2 is formed from a fluid-impermeable film, which when the insert 2 is introduced into a hygiene item or into the upper side of an absorbent element of a hygiene item, forms a separating means 8, which separates the analysis device 4 from the absorbent element materials of the hygiene item and prevents bodily fluids,

specifically urine, which initially pass from a user of the hygiene item into the absorbent element of the hygiene item, from being able to reach the analysis device 4 from there. Absorbent element materials in modern hygiene items contain ingredients, for example, superabsorbent polymer materials which give off substances into the bodily fluid and thereby change its composition, particularly when measuring the pH, nitrite, leukocyte, glucose or electrolyte values. The reading determined in the analysis device would be falsified.

It is therefore proposed with the invention that the analysis device be divided or separated from the absorbent element materials in the hygiene item by means of the separating means 8. As already mentioned, the insert 2 is used for this purpose. The insert 2 has sidewalls 10 extending up on the body side of a user. Edges 12 of the insert 2, which connect to the sidewalls 10, are folded over to the inside on one top side 14. The edges 12 are fixed in this position, specifically by means of an adhesive or welded joint 16, which is only suggested in Figures 1 and 3.

The insert 2 comprises, in addition to the analysis device 4, an absorption and transfer layer 18 to absorb and transfer bodily fluid which has been passed directly by a user of the hygiene item. This layer 18 is advantageously formed from a material which has adequate holding capacity to retain the bodily fluid and at the same time possesses sufficient capillary action to ensure that bodily fluid is transported within the layer 18, and in so doing without releasing substances which can have an influence on the result of the measurement to be made in the analysis device 4. Cellular materials are used advantageously, that is, preferably air-layered natural cellulose, but a viscose mat reinforced with bi-component fibers, for instance polyethylene, polypropylene, would be conceivable and advantageous.

The storage layer 18 is used for absorbing and transferring the bodily fluid to the analysis device 4, it also ensures that an adequate quantity of the bodily fluid to be analyzed is captured and kept in temporary storage.

As can be seen from Figure 3, the analysis device 4 is positioned against one inner side 20 of the fluid-impermeable film 6 which forms the separating means 8. The film 6 is transparent in this area, so that it is possible to examine the analysis device 4 from the underside 22 of the insert 2. In order to take a reading

from the analysis device 4, it has a visual display unit 24, which is visible through the transparent area 26 which forms a type of viewing window. The display unit 24 advantageously comprises colored indicators which undergo and display a color reaction corresponding to the concentration of a substance to be ascertained, which then by assignment to predetermined color panels enable the user of the analysis device 4 to evaluate the reading.

The insert 2 is advantageously let into the upper side of an absorbent element of a hygiene item. After the hygiene item has been used, the entire insert 2 is detached from the hygiene item, which can then be thrown away. The insert 2 can then be conveniently folded together, where the film 6 forming the separating means 8 forms the outer side. By means of the aforementioned transparent area 26 it is possible to take a look at or read the display unit 24 of the analysis device 4.

In order to fasten the insert 2 detachably to the hygiene item, the latter has touch-sensitive or adhesive means of attachment 28 on the side facing away from the body in use, which in the instance shown, for example, are supplied as strips extending the entire longitudinal length of the insert 2.

Figure 4 shows an insert 2 constructed corresponding to Figures 1 to 3, which differs from those described previously in that it has no dish-shaped edges extending up and turned over to the inside, but the separating means 8 delimiting the insert 2 is formed as a basically flat film 6. This insert 2 for the hygiene item, which is not shown, is therefore preferably applied to an upper side of the absorbent element of the hygiene item facing the body and fastened there detachably.